

## PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:  
LEONA L. LAUDER  
235 MONTGOMERY STREET  
SUITE 1026  
SAN FRANCISCO, CA 94104-3008

PCT

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL SEARCH REPORT AND  
THE WRITTEN OPINION OF THE INTERNATIONAL  
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

|   |  |  |
|---|--|--|
| Applicant's or agent's file reference<br>MST-2390 PCT |  | Date of mailing<br>(day/month/year) <b>27 SEP 2004</b>                     |
| International application No.<br>PCT/US04/34573       |  | FOR FURTHER ACTION See paragraphs 1 and 4 below                            |
| Applicant<br>BAYER HEALTHCARE                         |  | International filing date<br>(day/month/year) 18 October 2004 (18.10.2004) |

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

**Filing of amendments and statement under Article 19:**

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

**When?** The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

**Where?** Directly to the International Bureau of WIPO, 34 chemin des Colombettes  
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70.

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

|  |  |
|--|--|
| Name and mailing address of the ISA/ US<br>Mail Stop PCT, Attn: ISA/US<br>Commissioner for Patents<br>P.O. Box 1450<br>Alexandria, Virginia 22313-1450<br>Facsimile No. (703) 305-3230 | Authorized officer<br><i>Valerie Bell-Harris</i><br>MISOOK YU, Ph.D.<br>Telephone No. 571-272-1600 |
|--|--|

# INTERNATIONAL SEARCH REPORT

International application No. — — — —

PCT/US04/34573

## Box No. I Nucleotide and/or amino acid sequence(s) (Continuation of item 1.b of the first sheet)

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, the international search was carried out on the basis of:

a. type of material



a sequence listing



table(s) related to the sequence listing

b. format of material



on paper



in electronic form

c. time of filing/furnishing



contained in the international application as filed



filed together with the international application in electronic form



furnished subsequently to this Authority for the purposes of search

2. ☒

In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

# INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US04/34573

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : G01N 33/534; C12Q 1/68

US CL : 436/518, 501; 435/6, 7.1

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 436/518, 501; 435/6, 7.1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
Please See Continuation Sheet

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages                      | Relevant to claim No. |
|------------|---|-----------------------|
| X          | US 6,027,887A(ZAVADA et al) 22February 2000 (22.02.2000), especially SEQ ID NO:1, abstract, columns 3-5 | 1-24                  |



Further documents are listed in the continuation of Box C.



See patent family annex.

| Special categories of cited documents:  |  |
|---|--|
| "A" document defining the general state of the art which is not considered to be of particular relevance  | "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention  |
| "E" earlier application or patent published on or after the international filing date   | "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone   |
| "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| "O" document referring to an oral disclosure, use, exhibition or other means  | "&" document member of the same patent family  |
| "P" document published prior to the international filing date but later than the priority date claimed  |  |

Date of the actual completion of the international search

10 September 2005 (10.09.2005)

Date of mailing of the international search report

27 SEP 2005

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Authorized officer

MISOOK YU, Ph.D.

Telephone No. 571-272-1600

# INTERNATIONAL SEARCH REPORT

International application  
PCT/US04/34572

Continuation of B. FIELDS SEARCHED Item 3:  
nucleic acid sequence databases, Dialog (155), West (USPT, DWPI)  
Search terms: SEQ ID NO:1, MN, prognosis, preneoplastic and neoplastic diseases

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:  
LEONA L. LAUDER  
235 MONTGOMERY STREET  
SUITE 1026  
SAN FRANCISCO, CA 94104-3008

# PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

|   |   |   |
|---|---|---|
| Applicant's or agent's file reference<br><b>MST-2390 PCT</b>  |   | Date of mailing<br>(day/month/year) <b>27 SEP 2005</b>                |
| <b>FOR FURTHER ACTION</b><br>See paragraph 2 below  |   |   |
| International application No.<br><b>PCT/US04/34573</b>  | International filing date (day/month/year)<br><b>18 October 2004 (18.10.2004)</b> | Priority date (day/month/year)<br><b>16 October 2003 (16.10.2003)</b> |
| International Patent Classification (IPC) or both national classification and IPC<br><b>IPC(7): G01N 33/534; C12Q 1/68 and US Cl.: 436/518, 501; 435/6, 7.1</b> |   |   |
| Applicant<br><b>BAYER HEALTHCARE</b>  |   |   |

1. This opinion contains indications relating to the following items:

- ☒ Box No. I      Basis of the opinion
- ☐ Box No. II      Priority
- ☐ Box No. III      Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV      Lack of unity of invention
- ☒ Box No. V      Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI      Certain documents cited
- ☐ Box No. VII      Certain defects in the international application
- ☐ Box No. VIII      Certain observations on the international application

## 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

|  |  |  |
|--|--|--|
| Name and mailing address of the ISA/ US<br>Mail Stop PCT, Attn: ISA/US<br>Commissioner for Patents<br>P.O. Box 1450<br>Alexandria, Virginia 22313-1450<br>Facsimile No. (703) 305-3230 | Date of completion of this opinion<br><br>10 September 2005 (10.09.2005) | Authorized officer<br><i>Valerie Bell-Harris</i><br>MISOOK YU, Ph.D.<br><br>Telephone No. 571-272-1600 |
|--|--|--|

Form PCT/ISA/237 (cover sheet) (April 2005)

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No. \_\_\_\_\_

PCT/US04/34573

**Box No. I Basis of this opinion**

1. With regard to the language, this opinion has been established on the basis of:
  - ☒ the international application in the language in which it was filed
  - ☐ a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material
    - ☒ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material
    - ☒ on paper
    - ☒ in electronic form
  - c. time of filing/furnishing
    - ☒ contained in the international application as filed.
    - ☒ filed together with the international application in electronic form.
    - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US04/34578

**Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

|                               |                    |     |
|-------------------------------|--------------------|-----|
| Novelty (N)                   | Claims <u>NONE</u> | YES |
|                               | Claims <u>1-24</u> | NO  |
| Inventive step (IS)           | Claims <u>NONE</u> | YES |
|                               | Claims <u>1-24</u> | NO  |
| Industrial applicability (IA) | Claims <u>1-24</u> | YES |
|                               | Claims <u>NONE</u> | NO  |

**2. Citations and explanations:**

Claims 1-24 lack novelty under PCT Article 33(2) as being anticipated by US 6,027,887 (Zavada et al). Zavada et al teach SEQ ID NO :1, identical to the instant SEQ ID NO:1 recited in the instant claim 1, and is MN/CA9 cDNA from MN/CA9 gene. Zavada et al., also teach that MN/CA9 gene is a oncogene whose expression is related to bad prognosis of preneoplastic/neoplastic disease at columns 3-5.

Claims 1-24 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.